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10/551,256	09/27/2005	Paul Kenneth Rand	PB60091USW	5474
23347 7590 11/12/2008 GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398				
EXAMINER WRIGHT, MADISON L				
ART UNIT 4137		PAPER NUMBER		
NOTIFICATION DATE 11/12/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/551,256

Applicant(s)

RAND, PAUL KENNETH

Examiner

Madison L. Wright

Art Unit

4137

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-29 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 27 September 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date 9/27/2005
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 9/27/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: **26** in Figure 2.
3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the **third state of the capsule in which the chamber is open to the outside environment and there is a partial seal at the vent, the partial seal being gas pervious but powder product impervious** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing

figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. The term "generally" in claims 6 and 7 is a relative term which renders the claim indefinite. The term "generally" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.
- In **claim 6**, the applicant describes the capsule as being "generally" cylindrical which makes the shape of the capsule indefinite.

- In **claim 7**, the applicant describes the chain link as extending "generally" radially outward which makes the direction that the chain link extends indefinite.

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8. **Claim 12** recites the limitation "the first chamber", "the flange portion", and "the second chamber" in the last two lines of the claim. There is insufficient antecedent basis for this limitation in the claim. For the purpose of the examination the examiner assumes the first chamber is the top chamber, the flange portion separates the top and bottom chambers, and the second chamber is the bottom chamber.

9. **Claims 13-17** recites the limitation "the outside environment" and "the base" in the last five lines of claim 13. There is insufficient antecedent basis for this limitation in the claim. For the purpose of the examination the examiner assumes the outside environment is anything outside of the capsule and the base is the bottom of the chamber.

10. **Claims 3, 27, and 28** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear to the examiner if the applicant is claiming one link or multiple links because the applicant claims one link in claim 3 and multiple links in the dependent claim 27.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 3, 5-9, 11, 18-22, and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by WIPO Publication WO 01/30430 A1 to *Braithwaite et al.* ("*Braithwaite*").

As to **claim 1**, *Braithwaite* discloses chain linked capsules (pg. 2, lines 7-8 and pg. 4, lines 10-14). The examiner views the medicament dosage unit 1 of *Braithwaite* as the capsule of the application.

As to **claim 3**, *Braithwaite* discloses a capsule (pg. 2, lines 7-8) and a chain link (pg. 4, lines 10-14) for the capsule.

As to **claim 5**, *Braithwaite* discloses wherein the chain link extends from a base of the capsule (cartridge 112, Fig. 12a-b).

As to **claim 6**, *Braithwaite* discloses wherein the capsule is generally cylindrical (Fig. 3).

As to **claim 7**, *Braithwaite* discloses wherein the chain link extends generally radially outward from the capsule (Fig. 12a).

As to **claim 8**, *Braithwaite* discloses wherein the capsule comprises a sleeve (sleeve 12) which is provided with an internal chamber (container 2) for holding a powder product (medicament 11) within the capsule (Fig. 3).

As to **claim 9**, *Braitwaite* discloses wherein the sleeve comprises a first opening at a first end thereof and a second opening at an opposite end thereof (Fig. 3).

As to **claim 11**, *Braitwaite* discloses wherein the capsule comprises a sleeve (sleeve 12, Fig. 3) and a piston (cap 6, Fig. 3).

As to **claim 18**, *Braitwaite* discloses wherein the capsule (container 102) comprises an opening (top opening, Fig. 12) at an end thereof of a size corresponding with a protrusion (sleeve 108) on the end of the chain link (sleeve 108, cartridge 112).

As to **claim 19**, *Braitwaite* discloses wherein the protrusion (sleeve 108) is a tubular portion having a hole therethrough (Fig. 12).

As to **claim 20**, *Braitwaite* discloses wherein the chain link (sleeve 108, cartridge 112) is pivotally connected to the capsule (container 102) at one end of the chain link (Fig. 12a-12b). The examiner views that the capsule and the chain link are pivotally connected in that container 102 can pivot or rotate within sleeve 108.

As to **claim 21**, *Braitwaite* discloses wherein the chain link is integral with the capsule (Fig. 12b).

As to **claim 22**, *Braitwaite* discloses wherein the chain link is pivotally connectable to a capsule at both ends of the chain link (Fig. 12b). The examiner views that the capsule and the chain link are pivotally connected in that container 102 can pivot or rotate within sleeve 108.

As to **claim 27**, *Braitwaite* discloses wherein the chain links are pivotally connected to the capsules to form chain linked capsules (Fig. 12a-12b). The examiner

views that the capsule and the chain link are pivotally connected in that container 102 can pivot or rotate within sleeve 108.

As to **claim 28**, *Braithwaite* discloses the plurality of capsules and chain links of claim 27 provided within a channel. *Braithwaite* discloses that the capsules are intended for the inhalation device, such as the TECHNOHALER, which implies that the capsules and the chain links are in a channel (pg. 4, lines 16-37).

As to **claim 29**, *Braithwaite* discloses an inhalation device containing chain-linked capsules which contain an inhalable product (pg. 5, lines 10-14).

13. Claims 1, 3, 5-8, 10-11, 18-23, 27, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,095,587 to *Ishikawa*.

As to **claim 1**, *Ishikawa* discloses chain linked capsules (Fig. 5, col. 2, lines 53-57).

As to **claim 3**, *Ishikawa* discloses a capsule (capsule 3) and a chain link (links 4 and 4' and chains 8) for the capsule.

As to **claim 5**, *Ishikawa* discloses wherein the chain link (links 4 and 4' and chains 8) extends from a base (proximate 4') of the capsule.

As to **claim 6**, *Ishikawa* discloses wherein the capsule is generally cylindrical (Fig. 4B).

As to **claim 7**, *Ishikawa* discloses wherein the chain link (links 4 and 4' and chains 8) extends generally radially outward from the capsule (Fig. 4A).

As to **claim 8**, *Ishikawa* discloses wherein the capsule comprises a sleeve (cylindrical case 2) which is provided with an internal chamber (magnet 1) for holding a powder product within the capsule (Fig. 4A). The examiner views that the internal chamber 1 is capable of holding powder.

As to **claim 10**, *Ishikawa* discloses wherein the capsule (container 3) comprises two chambers separated by a flange portion (Fig. 4A), the first of the chambers (magnet 1) being for containing a powder product and the second of the chambers (where screw threads are found in Fig. 4A) being for connecting a chain link thereto.

As to **claim 11**, *Ishikawa* discloses wherein the capsule comprises a sleeve (cylindrical case 2) and a piston (screw part 7).

As to **claim 18**, *Ishikawa* discloses wherein the capsule (container 3) comprises an opening at an end thereof (screw part 7) of a size corresponding with a protrusion (link 4, screw part 7, cap 5) on the end of the chain link (chains 8).

As to **claim 19**, *Ishikawa* discloses wherein the protrusion (link 4, screw part 7, cap 5) is a tubular portion having a hole (4, Fig. 4A) therethrough.

As to **claim 20**, *Ishikawa* discloses wherein the chain link is pivotally connected to the capsule at one end of the chain link (Fig. 5).

As to **claim 21**, *Ishikawa* discloses wherein the chain link is integral with the capsule (Fig. 4A).

As to **claim 22**, *Ishikawa* discloses wherein the chain link is pivotally connectable to a capsule at both ends of the chain link (Fig. 5).

As to **claim 23**, *Ishikawa* discloses wherein the chain link (chains 8) comprises two tubular portions provided at ends of a flange (straight piece between each round portion, Fig. 5).

As to **claim 27**, *Ishikawa* discloses wherein the chain links are pivotally connected to the capsules to form chain linked capsules (Fig. 5).

As to **claim 29**, *Ishikawa* discloses an inhalation device containing chain-linked capsules which contain an inhalable product. The capsules contain some air which is an inhalable product.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Braitwaite*.

As to **claim 2**, *Braitwaite* discloses the claimed invention except for wherein the capsules have a length of no more than about 15mm and a width of no more than about 8mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have small capsules because the powder medication is small, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

As to **claim 4**, *Braitwaite* discloses the claimed invention except for wherein the capsule has a length of no more than about 15mm and a width of no more than about 8mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have small capsules because the powder medication is small, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

16. Claims 2, 4, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Ishikawa*.

As to **claim 2**, *Ishikawa* discloses the claimed invention except for wherein the capsules have a length of no more than about 15mm and a width of no more than about 8mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have small capsules because the powder medication is small, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

As to **claim 4**, *Ishikawa* discloses the claimed invention except for wherein the capsule has a length of no more than about 15mm and a width of no more than about 8mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have small capsules because the powder medication is small, since it has been held that where the general conditions of a claim are disclosed in the

prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

As to **claim 24**, *Ishikawa* discloses the claimed invention except for wherein the first tubular portion is of a first diameter and the second tubular portion is of a second diameter. It would have been an obvious matter of design choice to have changed the size of chains 8, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

As to **claim 25**, *Ishikawa* discloses the claimed invention except for wherein both tubular portions are hollow, the second tubular portion having an internal diameter corresponding generally to the outside diameter of the first tubular portion. It would have been an obvious matter of design choice to have changed the size of chains 8, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

As to **claim 26**, *Ishikawa* discloses the claimed invention except for wherein the second tubular portion has an outside diameter corresponding generally with the diameter of an opening in an end of the capsule. It would have been an obvious matter of design choice to have changed the size of chains 8, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

17. Claims 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Braitwaite* in view of U.S. Patent No. 1,410,556 to *Dorment*.

As to **claims 11-14**, all of the claim limitations are discussed with respect to **claim 3** above, except for wherein the capsule comprises a sleeve and a piston; wherein the piston is adapted to extend within the sleeve from a first end thereof, through the first chamber and the flange portion, and into the second chamber; wherein the sleeve and the piston are adapted to be displaced between a discharging position or state in which both a chamber of the capsule adapted to contain a powder product is open to the outside environment and a vent provided in the base of the chamber is open for allowing powder product from within the chamber to be sucked out of the chamber through a first opening to the outside environment and a sealing state in which both the chamber is sealed from the outside environment and the vent is closed; and wherein the base is a flange portion separating two chambers and the vent is provided through the flange portion.

Dorment discloses a piston (member 8) that extends within the sleeve (body 1) from a first end (Fig. 1) thereof, through the first chamber (passageway 2) and the flange portion (passageway 3), and into the second chamber (member 5). The examiner views that a flange is a rim for guiding one object with another ("flange." Merriam-Webster Online Dictionary. 2008. Merriam-Webster Online. 28 October 2008 <<http://www.merriam-webster.com/dictionary/flange>>). *Dorment* also discloses the sleeve (body 1) and the piston (member 8) are adapted to be displaced between a

discharging position or state in which both a chamber of the capsule adapted to contain a powder product is open to the outside environment and a vent provided in the base of the chamber is open for allowing powder product from within the chamber to be sucked out of the chamber through a first opening to the outside environment (Fig. 2) and a sealing state in which both the chamber is sealed from the outside environment and the vent is closed (Fig. 1). *Dorment* also discloses the base is a flange portion (passageway 3) separating two chambers (passageway 2 and member 5) and the vent is provided through the flange portion (Fig. 2). The vent begins at central opening 7 (Fig. 2) and the air is moved up the sleeve by the longitudinal extending passageways 11.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the capsules of *Braitwaite* with the sleeve and piston as taught by *Dorment* to construct a low cost inhaler (*Dorment*, pg. 2, lines 30-33).

As to **claim 15**, all of the claim limitations are discussed with respect to **claim 14** above, and further wherein in the sealing state, the piston of the modified *Braitwaite* device (as taught by *Dorment*) closes the vent to isolate the two chambers from each other.

Dorment discloses in the sealing state (Fig. 1), the piston closes the vent to isolate the two chambers from each other (Fig. 1; pg. 1, lines 97-102, pg. 2, lines 1-5). (The recited function is inherent in the operation of *Dorment*)

As to **claim 16**, all of the claim limitations are discussed with respect to **claim 13** above, and further wherein the capsule of the modified *Braitwaite* can be placed into a

third state in which the chamber is open to the outside environment and there is a partial seal at the vent, the partial seal being gas pervious but powder product impervious. The piston of the modified *Braitwaite* device (as taught by *Dorment*) is capable of being slightly opened so that no powder can escape through passageway 2.

As to **claim 17**, all of the claim limitations are discussed with respect to **claim 16** above, and further wherein the piston of the modified *Braitwaite* device (as taught by *Dorment*) has a circumferential array of longitudinal channels formed in a portion of the outer surface of the piston.

Dorment discloses one or more longitudinally extending passageways 11 that are on member 8 to allow air to enter the passageway 1 and pass into the chamber (pg. 2, lines 6-15).

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- WIPO Publication 01/17595 to Braithwaite discloses a similar powder dispensing mechanism.
- U.S. Patent 5,924,417 to Braithwaite discloses a similar powder dispensing mechanism.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Madison L. Wright whose telephone number is 571-270-7427. The examiner can normally be reached on Monday thru Friday, 8:00 to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ken Bomberg can be reached on 571-272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. L. W./
Examiner, Art Unit 4137

/David Isabella/ Supervisory Patent Examiner for Ken Bomberg, Art Unit 4137